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10/748,477	12/30/2003	Kay L. Grasso	CRNC.107715	7079

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EXAMINER
SQUIRES, ELIZA A

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	10/748,477	GRASSO ET AL.
Office Action Summary	Examiner	Art Unit	
	Eliza Squires	3626	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS,
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on _22 January 2009_.

2a) ☐ This action is **FINAL**.   2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) _1-7,26-29,41 and 46_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) _1-7, 26-29 and 41_ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on _12/30/09_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

       1. ☐ Certified copies of the priority documents have been received.

       2. ☐ Certified copies of the priority documents have been received in Application No. _____.

       3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage
application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _4/2/04_.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1.   Applicant's election of claims 1-7, 26-29, 41 and 46 in the reply filed on 22 January

2009 is acknowledged. Because applicant did not distinctly and specifically point out the

supposed errors in the restriction requirement, the election has been treated as an election

without traverse (MPEP § 818.03(a)).

2.   Claims 8-25, 30-40, 42-45, and 47-50 are withdrawn from further consideration pursuant

to 37 CFR 1.142(b) as being drawn to a nonelected subcombination, there being no allowable

generic or linking claim. Election was made **without** traverse in the reply filed on 22 January

2009.

Claim Rejections - 35 USC § 101

3.   35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or
> any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and
> requirements of this title.

4.   **Claims 1-7** are rejected under 35 U.S.C. 101. Based on Supreme Court precedent and

recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must

(1) be tied to a machine or (2) transform underlying subject matter (such as an article or

materials) to a different state or thing. In re Bilski et al, 88 USPQ 2d 1385 CAFC (2008);

Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978);

Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876).

        An example of a method claim that would <u>not</u> qualify as a statutory process would be a

claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim

should positively recite the particular machine to which it is tied, for example by identifying the

apparatus that accomplishes the method steps, or positively recite the subject matter that is being

transformed, for example by identifying the material that is being changed to a different state.

Here, applicant's method steps fail the first prong of the new Federal Circuit decision

since they are not tied to a machine and can be performed without the use of a

particular machine.

The recitation of a "method in a computer system" in the preamble is insufficient to

overcome this rejection, because it is not clear which, if any, method steps are being performed

by a computer processor.

5.   **Claims 26-29 and 41** are rejected under 35 U.S.C. 101 because the claims are directed

towards software per se which is non-statutory. A system is an apparatus comprised of various

structural components, these claims, however, recite different computer programming elements

or modules for performing certain functions. Being absent any structural components such as a

computer system, memory, computer readable medium, etc., the claims recite simply descriptive

material, i.e. software per se. Claim 41 is similarly rejected as the claim may be directed towards

computer software per se.

Claim Rejections - 35 USC § 112

6.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the
> subject matter which the applicant regards as his invention.

7.   **Claims 1-7, 41, and 46** are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention.

        The claims contain conditional statements such as "if so, outputing information…" "even

though it is too soon…" "wherein it is not safe…" however the claims offer no alternative for if

the condition was not met. These statements render the claims indefinite.

8.   Claim element "means for recieving" "means for determining" is a means (or step) plus

function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description

fails to clearly link or associate the disclosed structure, material, or acts to the claimed function

such that one of ordinary skill in the art would recognize what structure, material, or acts perform

the claimed function.

        Applicant is required to:

        (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus

function limitation under 35 U.S.C. 112, sixth paragraph; or

        (b) Amend the written description of the specification such that it clearly links or

associates the corresponding structure, material, or acts to the claimed function without

introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 102

9.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on
sale in this country, more than one year prior to the date of application for patent in the United States.

10.   **Claims 1-7, 26-29, 41, and 46** are rejected under 35 U.S.C. 102(a) as being anticipated

by anticipated by "Combining Tabular, Rule-Based, and procedural Knowledge in Computer-

Based Guidelines for Childhood Immunization" by *Miller et al.*

11.   **As to claim 1,** *Miller* discloses a method in a computer system for preventing one or

more immunizations from being administered to a person too early, the method comprising:

        receiving the immunizations to be administered to a person (*Miller* abstract and page

212);

        determining whether it is too soon to administer the immunization (*Miller* page 221

wherein the program determines whether "the dose is not yet due"); and

        if so, outputting information that the immunization being administered too soon (*Miller*

page 214 wherein the system outputs doses which were given to soon).

12.   **As to claim 2,** see the discussion of claim 1, additionally, *Miller* discloses the method of

further comprising:

        determining whether it is still safe to administer the immunization even though it is too

soon to administer the immunization (*Miller* page 219 wherein the system determines a

recommended age (at which the dose should be scheduled) and a minimum acceptable age (at

which the dose may be given if the child happens to be at the clinic)).

13.   **As to claim 3,** see the discussion of claims 1 and 2, additionally, *Miller* discloses the
method wherein if it is safe to administer the immunization, outputting information that it is safe
to administer the immunization (*Miller* page 225 figure 9 and pages 214 and 215).

14.   **As to claim 4,** see the discussion of claim 1 and 2, additionally, *Miller* discloses the
method wherein if it is not safe to administer the immunization, outputting information that it is
not safe to administer the immunization (*Miller* page 225 figure 9 and pages 214 and 215).

15.   **As to claim 5,** see the discussion of claim 1, additionally, *Miller* discloses the method
further comprising:

        obtaining information regarding the safe timing of immunizations from a database (*Miller*
abstract and page 219).

16.   **As to claim 6,** see the discussion of claim 1 and 5, additionally, *Miller* discloses the
method further comprising:

        obtaining information from an electronic medical record of the person stored within a
comprehensive healthcare system (*Miller* page 212).

17.   **As to claim 7,** see the discussion of claims 1 and 5-6, additionally, *Miller* discloses the
method further comprising:

        utilizing the information from the electronic medical record of the person and the
information regarding safe timing of immunizations to determine whether an immunization is
being administered too soon (*Miller* page 212, 214-215, and page 219).

18.   **As to claim 26,** *Miller* discloses a system in a computerized environment for preventing

one or more immunizations from being administered to a person too early, the system

comprising:

    a receiving module for receiving the immunizations to be administered to a person

(*Miller* abstract and page 212);

    a determining module for determining whether it is too soon to administer the

immunization (*Miller* page 221 wherein the program determines whether "the dose is not yet

due"); and

    an outputting module for outputting information that the immunization being

administered too soon (*Miller* page 214 wherein the system outputs doses which were given to

soon).

19.   **As to claim 27,** see the discussion of claim 26, additionally, *Miller* discloses the system

further comprising a second determining module for determining whether it is still safe to

administer the immunization even though it is too soon to administer the immunization (*Miller*

page 219 wherein the system determines a recommended age (at which the dose should be

scheduled) and a minimum acceptable age (at which the dose may be given if the child happens

to be at the clinic)).

20.   **As to claim 28,** see the discussion of claim 26-27, additionally, *Miller* discloses the

system wherein if it is safe to administer the immunization, outputting information that it is safe

to administer the immunization (*Miller* page 225 figure 9 and pages 214 and 215).

21.   **As to claim 29,** see the discussion of claim 26-27, additionally, *Miller* discloses the

system wherein if it is not safe to administer the immunization, outputting information that it is

not safe to administer the immunization (*Miller* page 225 figure 9 and pages 214 and 215).

22.   **As to claim 41,** *Miller* discloses a system in a computerized environment for preventing

one or more immunizations from being administered to a person too early, the system

comprising:

        means for receiving the immunizations to be administered to a person (*Miller* abstract

and page 212);

        means for determining whether it is too soon to administer the immunization (*Miller* page

221 wherein the program determines whether "the dose is not yet due"); and

        if so, outputting information that the immunization being administered too soon (*Miller*

page 214 wherein the system outputs doses which were given to soon).

23.   **As to claim 46,** *Miller* discloses a computer-readable medium having computer-

executable instructions for performing a method, the method comprising:

        receiving the immunizations to be administered to a person (*Miller* abstract and page

212);

        determining whether it is too soon to administer the immunization (*Miller* page 221

wherein the program determines whether "the dose is not yet due");   and

        if so, outputting information that the immunization being administered too soon (*Miller*

page 214 wherein the system outputs doses which were given to soon).

Conclusion

24.   The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure.

a.   "All in One Shot" by Paul Swiech discusses a "…computer records program that

would flag a vaccine if a patient already has received it or <u>would get it too soon</u>".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliza Squires whose telephone number is (571)270-7052. The examiner can normally be reached on Monday through Friday 8 am - 4 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eliza Squires/
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3/17/09

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